Notice of Allowability	Application No.	Applicant(s)	
	10/083,576	MALKAS ET AL.	
	Examiner	Art Unit	
	Sheela J. Huff	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *5/3/07 and 11/22/06*.

2. ☒ The allowed claim(s) is/are *1-11 and 16-19 renumbered as 1-15*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 4/28/07; 4/12/07; 11/22/06; 5/15/07
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joe Morales on 5/15/07.

The application has been amended as follows:

Claims 13-15 have been cancelled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesday and Thursday from 5:30am to 1:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sheela J Huff
Primary Examiner
Art Unit 1643

sjh

AMENDMENT

Listing of Claims

Please amend the claims as follows:

1. (Currently Amended) A method for purifying cancer-specific Proliferating Cell Nuclear Antigen (csPCNA) comprising the steps of:

   (A) obtaining a tissue or body fluid sample comprising csPCNA;

   (B) contacting said sample with a peptide comprising the amino acid sequence
   LeuLysGlnLeuAspAlaGlnGlnThrGlnLeuArgIleAspSerPhePheArgLeu
   AlaGlnGlnGluLysGluAspAlaLysArg (SEQ ID No:1),
   wherein said peptide is immobilized on a solid support and binds to said csPCNA to form a peptide-csPCNA complex; and

   (C) isolating csPCNA from said peptide-csPCNA complex so as to purify said csPCNA.

2. (Original) The method of Claim 1, wherein prior to step (B) the thus obtained tissue or body fluid sample of step (A) is subjected to a process comprising:

   (1) homogenizing cells constituting said tissue or body fluid to obtain a homogenate (H);

   (2) separating said H into a nuclear pellet fraction (NP) and a cytosolic fraction (S1);

   (3) extracting nuclei from said NP to obtain a nuclear extract (NE);

   (4) subjecting said S1 to centrifugation to obtain a post-mitochondrial cytosolic supernatant (S2);

   (5) subjecting said S2 to centrifugation to obtain a post-mitochondrial/post-microsomal cytosolic supernatant (S3);

   (6) combining said NE and said S3 to form an NE/S3 fraction, applying the resulting NE/S3 fraction to a weak anion exchange matrix column and collecting the flow through (PCFT);

(7) applying the resulting PCFT to a hydrophobic chromatography matrix column, eluting the column with buffer comprising ethylene glycol and collecting the eluant (PSE);

(8) dialyzing out ethylene glycol present in the PSE to obtain a dialyzate; and

(9) applying the resulting dialyzate to a strong anion exchange matrix column, eluting with a dialyzate buffer comprising a salt gradient, and collecting and pooling PCNA-containing fractions to obtain said sample.

3. (Previously Presented) The method of Claim 1 or 2, wherein said tissue or body fluid sample of step (A) further comprises native PCNA (nPCNA), said nPCNA does not bind to said peptide in step (B), whereas said csPCNA binds to said peptide in step (B) to form a peptide-csPCNA complex and in step (C) isolating csPCNA is effected using an elution buffer whereby csPCNA is eluted from said csPCNA-complex.

4. (Original) An immunoassay for detecting csPCNA comprising:

(1) contacting a test sample with a peptide comprising the amino acid sequence LeuLysGlnLeuAspAlaGlnGlnThrGlnLeuArgIleAspSerPheP heArgLeuAlaGlnGlnGluLysGluAspAlaLysArg (SEQ ID No:1), which has been immobilized on a solid support so as to bind csPCNA to said peptide to form a peptide-csPCNA complex; and

(2) contacting said peptide-csPCNA complex with an anti-PCNA antibody and detecting binding of said antibody to said complex.

5. (Original) The immunoassay of Claim 4, wherein said assay is an ELISA and

said antibody is labeled with a detectable enzyme.

6. (Original) The immunoassay of Claim 5, wherein said enzyme is horse radish peroxidase.

7. (Original) The immunoassay of Claim 5, wherein said peptide is a fusion protein comprising said peptide and Glutathione-S-Transferase.

8. (Previously Presented) The immunoassay of Claim 7, wherein said fusion protein is biotinylated and immobilized on said solid support via streptavidin-coated on said solid support.

9. (Currently Amended) The method of Claim 1, wherein the tissue or body fluid sample obtained is afflicted with a cancer selected from the group consisting of carcinomas, sarcomas, lymphomas, [[or]] and leukemias.

10. (Currently Amended) The method of Claim 9, wherein the tissue or body fluid sample obtained is selected from the group consisting of cervical, mammary glands, esophageal, glial cells, lung, stomach, intestine, prostate, white blood cells, urine, serum, [[or]] and whole blood.

11. (Currently Amended) The method of Claim 1, wherein said peptide is a fusion protein comprising said peptide and at least one of Glutathione-S-Transferase, Calmodulin Binding protein, [[and]] or oligo (6X) histidine.

12. (Cancelled)

13. (Withdrawn) The method of Claim 3, further comprising the step of identifying the site(s) on the PCNA polypeptide that is (are) modified in nPCNA and lacking from csPCNA.

14. (Withdrawn) The method of Claim 13, further comprising the step of identifying the metabolic pathways that mediate the addition or removal of this (these) post-translation modifications.

15. (Withdrawn) The method of Claim 1, further comprising the step of developing specific inhibitors for csPCNA.

12 ~~16~~. (Currently Amended) The immunoassay of Claim 4, wherein the test sample is afflicted with a cancer selected from the group consisting of carcinaomas, sarcomas, lymphomas, [[or]] and leukemias.

13 ~~17~~. (Currently Amended) The immunoassay of Claim 12 ~~16~~, wherein the test sample is obtained by selecting from the group consisting of cervical, mammary glands, esophageal, glial cells, lung, stomach, intestine, prostate, white blood cells, urine, serum, [[or]] and whole blood.

14 ~~18~~. (Currently Amended) The immunoassay of Claim 4, wherein said immunoassay is selected from the group consisting of radio-immunoassay, dot blot assay, slot blot assay, immunoprecipitation, protein quantification, imunno-PCR, [[or]] and Western blot.

15 ~~19~~. (New) The method of Claim 1, further comprising the step of producing antibodies (monoclonal or polyclonal) specific for csPCNA from said isolated and purified csPCNA.